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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,007

09/25/2003

Wendy H. Raskind

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT

PAPER NUMBER

1634

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/671,007	<b>Applicant(s)</b> RASKIND ET AL.	
	<b>Examiner</b> Diana B. Johannsen	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6 and 43-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6 and 43-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **FINAL ACTION**

1. This action is responsive to the Amendment filed December 12, 2008. Claims 1 and 4 have been amended and claims 1-2, 4-6, and 43-46 are now pending and under consideration. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and/or objections not reiterated in this action have been withdrawn. **This action is FINAL.**
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restrictions***

3. Applicant's election with traverse of the sequence of exon 4 in the reply filed on January 14, 2008 is again acknowledged.
4. With regard to claim 43, nucleic acid sequences other than the elected sequence (i.e., the sequence corresponding to exon 4) noted above remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the replies filed on September 28, 2007 and January 14, 2008.

### ***Declaration under 37 CFR 1.132***

5. The Declaration under 37 CFR 1.132 filed December 12, 2008 is sufficient to overcome the rejection of claims 1-2, 4-6, and 43-46 under 35 USC 102(a) based upon Chen et al set forth in the prior Office action.

***Claim Rejections - 35 USC § 112, first paragraph***

6. Claims 1-2, 4-6, and 43-46 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods comprising identifying the H101Y and/or S119P PKC gamma gene mutations in a human subject and “confirming” those mutations as being associated with adult onset cerebellar ataxia in a human subject, does not reasonably provide enablement for methods comprising identifying and “confirming” any other PKC gamma gene mutations as being associated with adult onset cerebellar ataxia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, for the reasons that were given in the prior Office action of September 10, 2008.

The reply traverses the rejection on the following grounds.

First, the response notes that the specification at page 5, lines 1-4 “defines the term ‘genetic mutation’ recited in claim 1 step (c) as an alteration of the wild-type protein kinase C gamma (PRKCG) sequence deposited in GENBANK, provided as SEQ ID NO: 3 that is not a recognized polymorphism (i.e., has a population frequency less than 1% in mammalian control subjects of the same species that do not exist in ataxia)”. This argument has been thoroughly considered but is not persuasive. While this definition provides further information with regard to what genetic mutations of the claims may not be (specifically, recognized polymorphisms), the definition provides no further information or guidance with regard to which mutations embraced by the claims could actually be “confirmed” as “associated with adult onset cerebellar ataxia. Thus, this

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portion of the specification does not provide further enabling guidance with regard to the invention that is actually claimed.

The response further argues that the examiner has acknowledged that the skill level in the relevant art is high, and has acknowledged that one of skill in the art could conduct screening methods aimed at determining whether other mutations associated with ataxia exist. This argument has also been thoroughly considered but is not persuasive. The fact that the examiner has acknowledged the ability of a skilled artisan to perform screening does not impact one way or the other on the ability of such an artisan to “confirm that the difference identified...is a genetic mutation associated with adult onset cerebellar ataxia” so as to achieve the required objective of “identifying a genetic mutation that is associated with adult onset cerebellar ataxia in a human subject.” The claimed invention is not directed to screening methods.

Finally, the response argues that the previously referenced post-filing date reference of Nolte et al “describes the identification of the mutation G63V in two human subjects exhibiting ataxia which was not detected in control chromosomes from 200 healthy subjects,” and further teaches additional mutations that co-segregate with ataxia that were identified subsequent to applicants effective filing date. These arguments have also been thoroughly considered but are not persuasive. First, it is noted that enablement of a claimed invention is evaluated as of the time of filing. Further, the type of ataxia described and discussed by Nolte et al is not that embraced by the claims, which require “adult onset cerebellar ataxia.” Thus, Nolte et al does not appear relevant

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to the issue of enablement of the present claims at the time applicant's invention was made.

Accordingly, applicant's arguments are not persuasive, and this rejection is maintained.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/  
Primary Examiner, Art Unit 1634